

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Kokubo et al.  
Filed: Concurrently Herewith  
For: SOLID PREPARATION COATED WITH A  
FILM COATING LAYER AND FILM COATING AGENT

April 26, 2001

Commissioner for Patents  
Washington, DC 20231

**PRELIMINARY AMENDMENT**

Dear Sir:

Please amend the above-identified application as follows:

**In The Claims:**

Please cancel Claims 2, 3 and 4.

Please add the following new Claims 6 through 30:

6. The solid preparation of claim 1, wherein said solid preparation is a tablet.
7. The solid preparation of claim 1, wherein said continuous film coating layer comprises one or more cellulose derivatives as film coating agents.
8. The solid preparation of Claim 7, wherein said cellulose derivative is selected from the group consisting of hydroxypropyl methyl cellulose (HPMC), methylcellulose (MC) and hydroxypropyl cellulose (HPC).

9. The solid preparation of Claim 8, wherein said cellulose derivative is hydroxypropyl methyl cellulose.

10. The solid preparation of claim 1, wherein said film coating layer comprises at least one colorant, and wherein at least a portion of said film coating layer is exposed to radiation under conditions sufficient to modify the color of said at least one colorant to provide a coating layer having at least two different colors.

11. The solid preparation of claim 10, wherein at least a portion of said film is exposed to radiation under conditions sufficient to fade the exposed colorant.

12. The solid preparation of claim 10, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant transparent.

13. The solid preparation of claim 10, wherein at least a portion of said film is exposed to radiation under conditions sufficient to render the exposed colorant semi-transparent.

14. The solid preparation of claim 10, wherein said colorant is a food additive.

15. The solid preparation of claim 1, wherein said solid preparation further comprises at least one additional layer underlying said continuous film coating, said at least one additional layer comprising a colorant to impart a color thereto that is different from the colors of the overlying continuous film coating layer.

16. The solid preparation of claim 1, wherein said film coating layer has two or more different colors.

17. The solid preparation of claim 1, wherein said film coating layer has a pattern of two or more different colors.

18. The solid preparation of claim 17, wherein said pattern comprises a logo.

19. The solid preparation of claim 17, wherein said pattern comprises a bar code.

20. The solid preparation of claim 17, wherein said pattern comprises letters.

21. A process for preparing a solid preparation coated with a continuous film coating layer having two or more different colors or a pattern of two or more different colors, the process comprising:

exposing a portion of a film coating layer comprising at least one colorant on a solid preparation to radiation to modify the color of the radiation exposed portion of the coating.

22. The process of claim 21, wherein said exposing step comprises irradiating a portion of said film coating layer to modify the color of the radiation exposed portion of the coating to form a coating layer having two or more different colors.

23. The process of claim 21, wherein said exposing step comprises irradiating a portion of said coating layer to modify the color of the radiation exposed portion of the coating to form a coating layer having a pattern of two or more different colors.

24. The process of claim 23, wherein said exposing step comprises irradiating said coating layer using a patterned photoresist.

25. The process of claim 21, further comprising applying said continuous film coating layer onto said solid preparation prior to said exposing step.

26. The process of claim 25, further comprising applying an underlying layer to said solid preparation prior to applying said continuous film layer, wherein said underlying layer comprises a colorant to impart a color thereto that is different from the colors of the overlying continuous film coating layer.

27. The process of claim 21, wherein said exposing step comprises exposing said film coating layer to ultraviolet radiation.

28. A film coating agent capable of forming a film coating layer on a solid preparation, the film coating agent comprising:

a film forming cellulose derivative; and

at least one colorant capable of modifying color upon exposure to radiation.

29. The film coating agent of claim 28, wherein said cellulose derivative is selected from the group consisting of hydroxypropyl methyl cellulose (HPMC), methylcellulose (MC) and hydroxypropyl cellulose (HPC).

30. The film coating agent of claim 28, wherein said colorant is a food additive.

DRAFT

REMARKS

The above amendments are made to more clearly define the invention under United States practice. Please enter this amendment prior to calculation of the filing fee.

Respectfully submitted,



Melissa B. Pendleton  
Registration No. 35,459

**CUSTOMER NO. 000826**  
**ALSTON & BIRD LLP**  
Bank of America Plaza  
101 South Tryon Street, Suite 4000  
Charlotte, NC 28280-4000  
Tel Charlotte Office (704) 444-1000  
Fax Charlotte Office (704) 444-1111  
**CLT01/4475805v1**

"Express Mail" Mailing Label Number EL836092385US  
Date of Deposit: April 26, 2001

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Box Patent Application, Commissioner for Patents, Washington, DC 20231.

  
Grace R. Rippy